REMARKS

In the Office Action dated November 30, 2004, Claims 1, 19, 22 and 23 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,438,244 to Juneau *et al.* ("Juneau"), and Claims 2-4, 20-21 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Juneau in combination with U.S. 5,825,896 to Leedom ("Leedom"). For the following reasons, it is believed that these rejections are overcome, and that all claims are allowable.

Regarding the rejection of Claim 1, this claim recites a Completely in the Canal (CIC) hearing aid body that is "adapted to *interchangeably fit inside the ear canal of either a right side or left side of an ear of a typical user* such that a distal end of the body is disposed proximally adjacent to a tympanic membrane of said user," and where the hearing aid body comprises "*a semi-rigid shell* that is shaped to conform to at least a first bend in an ear canal of *a typical user*." (Emphasis added).

As described in the present Specification at page 5, lines 8-18, the present invention provides a functional hearing aid body with a suitable shape capable of being located proximately adjacent the tympanic membrane and within the inner canal. Significantly, the shape is formed so that not only is the body capable of being comfortably inserted and left in position in the ear of a "typical user," such that "one-size-fits-all," but one size also fits either the left or right ear, i.e. a "uni-ear" or "non-specific" hearing aid device. Moreover, there is no need to customize the outer shell or to provide a soft compliant, in situ, formed outer mold around the shell. The shape of the hearing aid body is determined through a novel process which includes, *inter alia*, obtaining a plurality of sample ear impressions from the general populace and generating topological data from these samples; processing this data using generally available solid modeling software packages to mathematically generate volume dimensions representing the ear impressions; orienting and aligning these dimensions to create a single new set of volume dimensions which represents the intersection of all the sampled impressions; smoothing and truncating this shape so as to produce a "one-size-fits-all" shape; processing this shape and its "mirror image" shape to create a uni-shape, which after minor smoothing and radiusing operations produces a mold for a "uni-ear" hearing aid device. The mold can then be used to mass-produce a hearing aid body that can be comfortably worn in both the right and left ears of "typical users," or persons whose inner canal profile conforms substantially to a profile determined by obtaining impressions from a

statistically valid population of potential users. (See Specification at p. 5, line 16 through p. 6, line 12).

The Examiner's § 102(e) rejection of Claim 1 is overcome, because the cited Juneau patent fails to teach or suggest a hearing aid body that is "adapted to interchangeably fit inside the ear canal of either a right side or left side of an ear of a typical user." On the contrary, Juneau teaches a custom-made hearing device that is designed to fit in the ear canal of a specific side (right or left) of a specific user. As discussed in the Specification, unlike the present one-size-fits-all "uni-ear" hearing instruments, traditional hearing aids have generally been custom-made devices which require the long and cumbersome process of (1) testing the patient to quantify the spectral and intensity characteristics of one's hearing loss, (2) generating custom ear impressions for each ear to be fitted with an aid, (3) fabricating custom hearing instruments (for each ear) using the ear impressions as templates, and (4) typically modifying these parts to obtain an acceptable fit. (See Specification at p. 7, lines 22-27). This is precisely the type of custom-built hearing aid that is described in the cited Juneau reference, wherein a custom ear impression is taken of the patient's ear canal (see col. 5, line 36 though col. 6, line 1; Figs. 2-6); a custom hearing instrument is fabricated using the ear impression (female mould 15) as a template (see col. 7, lines 13-51; Figs. 9-17); and optionally, the hearing aid body may be returned for modifications (see col. 4, lines 10-13). It is inherent that the hearing aid devices of Juneau are not "uni-ear" devices, as in the present invention, since the devices of Juneau are intentionally designed to closely replicate the contours of each specific ear canal. Since the right and left side ear canals of a given patient are not identical, but are "mirror images" of one another, the Juneau devices cannot "interchangeably fit inside the ear canal of either a right side or left side of an ear," as in the present invention. Moreover, since the Juneau devices are custom-made for a specific patient's ear, they likewise cannot interchangeably fit in the ear of a "typical user," as in the case of the present invention.

Furthermore, applicants disagree with the Examiner's assessment that the Juneau reference discloses a "semi-rigid shell," as recited in Claim 1. Juneau itself distinguishes it's hearing device structure from the "shells" used in conventional hearing aids (see col. 2, lines 10-18). According to Juneau, the hearing devices of that patent consist of "solid" members which "eliminate[] void spaces," and actually embed the electronic components within an integrally-

formed polymeric fill material (see col. 3, line 63 through col. 4, line 1), rather than conventional "shells."

For the above reasons, it is believed that the Examiner's anticipation rejection of Claim 1 is overcome.

Independent Claims 19 and 22 contain similar limitations as Claim 1, and are novel with respect to the Juneau patent for substantially the same reasons as Claim 1. Claim 19 specifies a hearing aid body comprising a shell that is "shaped to be inserted into and useable inside the ear canal of a right ear or a left ear." In addition, the shell comprises a semi-rigid member that is "shaped to conform to at least a first bend in an ear canal of a typical user." This claim is clearly distinguishable from Juneau, since as discussed above, the Juneau device is a custom-made device designed for a specific ear canal (left *or* right, but not both), and can furthermore only be worn by a specific user, and not a "typical user."

Similarly, independent Claim 22 and its dependent, Claim 23, are novel over Juneau, since Juneau does not disclose a "hearing aid body formed of a semi-rigid shell . . . having a shape adapted to fit in the ear canal proximal to the tympanic region of either a right or left human ear, the shell being shaped to conform to at least a first bend in an ear canal of a typical user," as is recited in Claim 22. Moreover, Juneau does not disclose a hearing aid body having "a flexible tip retained at one end of the shell," as is also recited in Claim 22. In the Office Action, the Examiner asserts that element 42 of Juneau corresponds to the claimed "flexible tip." However, Juneau actually describes reference number 42 as an "opening" in the female mould 15 (which is not even part of the hearing device itself) used to form the hearing aid body. (See col. 7, lines 7-9). Thus, this element cannot anticipate the limitation of a "flexible tip," as recited in Claim 22, and Juneau does not otherwise teach the "flexible tip," as recited in this claim.

Accordingly, it is believed that the Examiner's rejections of Claims 1, 19, 22 and 23 under § 102(e) are all overcome.

In addition, the deficiencies of the Juneau reference described above in connection with independent Claims 1, 19 and 22 are not overcome by the secondary Leedom reference. The primary Juneau reference and the secondary Leedom reference cannot render the present claims obvious under § 103, since there is no suggestion to combine these references to produce hearing devices as presently claimed, and furthermore, any such attempted combination would be at odds

with the intended purposes of each of the references, and would render them both unsatisfactory for their intended purposes. The teachings of the primary Juneau reference has been discussed at length above. In essence, this patent purports to improve upon the design of the traditional, acrylic-shell custom designed hearing aid by the use of a solid "fill material" that is formed around, and completely embeds, the electronic components of the hearing aid. The fill material is softer than traditional shell materials, and purportedly accomplishes a "more faithful reproduction of the ear impression," thus minimizing the frequency and need for post-fitting modifications. (See e.g., col. 3, line 61 through col. 4, line 14). At essence, however, the hearing aid disclosed in Juneau is a custom built product that is specially designed for one specific ear of one specific user. One of the primary aims of Juneau is to make the device even *more faithful* to the contours of the user's ear than in similar prior art devices.

Leedom, on the other hand, takes a radically different approach to both the Juneau device and the one-size-fits-all uni-ear hearing aid body of the present invention. Leedom teaches a hearing device having a flexible circuit 12 with hearing aid components 14, 16, 18, 20 attached to the circuit. Half of the flexible circuit and hearing aid components are housed in a first boot 32 of flexible material, and half of the flexible circuit and hearing aid components are housed in a second boot 34 of flexible material. The two halves of the hearing aid are connected by the circuit 12, which serves as a hinge, so that the two boot portions 32 and 34 can articulate with respect to one another. In this way, the distal boot portion 32, which contains the speaker and battery, can turn around a bend in the ear, relative to the proximal boot portion 34, which contains the microphone and electronics.

There is no teaching or suggestion to combine the Juneau and Leedom hearing devices to produce the presently claimed invention, and it is difficult to envision how one would even attempt to combine these disparate teachings. Juneau and Leedom teach drastically different hearing aid designs. Juneau teaches a custom-built hearing device in which a solid "fill" material is formed out of a mould of the patient's ear canal. The Juneau device is designed to faithfully replicate the contour of a specific ear of a specific user to provide an especially tight fit in the user's ear canal. Leedom, by contrast, employs a pair of boot portions, connected by a flexible circuit, which are hinged relative to one another so that the distal boot portion, containing the receiver, can flex and turn around a bend in the ear canal. One skilled in the art would have no

suggestion or motivation to somehow attempt to combine these different designs. The entire purpose of the Juneau design is to provide an integral "solid" structure that more faithfully replicates the particular shape of the user's ear canal, and the articulating, hinged "boots" of Leedom is entirely inconsistent with this purpose. Similarly, Leedom teaches that the purposes of its device is to provide a simple, low cost design which "does not have to be specifically designed for the specific ear of the user." (See Leedom at col. 4, lines 64-67). As such, the custom molded polymeric body design of Juneau is entirely inconsistent with the stated purposes of the Leedom patent. Accordingly, there can be no motivation to combine these references to produce the one-size-fits-all uni-ear device of the present invention. In addition, neither of these references teaches or suggests a hearing aid having a shell that is shaped to conform to at least a first bend in an ear canal of a typical user.

For the reasons discussed above, it is respectfully submitted that the Examiner's rejections have all been overcome, and that Claims 1-4 and 19-24 are all allowable.

CONCLUSION

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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